

REMARKS

This application has been amended so as to place it in condition for allowance at the time of the next Office Action.

The Office Action rejects claim 16 under 35 U.S.C. 112, second paragraph as being indefinite. Underlying this rejection is the assertion that the adhesive is considered a tool or aid.

As part of the amendments discussed in detail below in connection with the rejections based on prior art, Applicant has amended claim 15, from which rejected claim 16 depends, to recite that the device includes means for adhering. Accordingly, the adhesive is part of the device as recited, and as a consequence does not constitute something apart from the device itself.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

The Office Action rejects claims 15, 17-19, 21, 22, 28, and 32-35 under 35 U.S.C. §103(a) as unpatentable over Groiso. Reconsideration and withdrawal of this rejection are respectfully requested for the following reasons:

The Office Action acknowledges that the applied Groiso reference fails to teach both the aluminum composition of the device as well as the recited layer of adhesive. As to

the latter, the Office Action takes the position that the Groiso reference discloses that it is known in the art to use adhesive to hold the splint in place while it cools and returns to its rigid state.

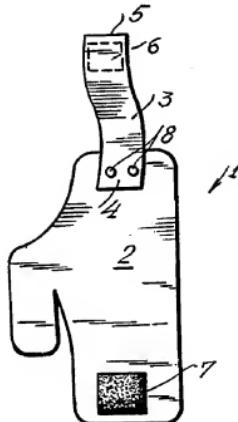
It is valuable to consider the context in which such statement is made in the Groiso reference. The paragraph within which the identified language appears is as follows:

Another kind of rigid orthosis comprises a thermoplastic material plate provided in the form of a large sheet, from which each splint has to be cut in the proper shape according to the injured human body member. Once cut, the plastic rigid splint must be perforated and binding ribbons riveted thereto. It is then sufficiently heated in a skillet, pan or other adequate means to transform the thermoplastic material to a soft state, whereafter the orthosis may be duly applied to and wrapped around the pertinent body member. Thereafter, the ribbons are wound around the splint and tied using a special adhesive to keep the splint in place until it cools and reverts to its normal rigid state.

Given such context, it is clear that the use of adhesive suggested by Groiso is decidedly not in connection with the securing the splint to the skin of the patient. Rather, the adhesive in question is applied only to a ribbon that is wound around the splint. Even then, the ribbon (and by extension the associated adhesive) is present only "until [the splint] cools and reverts to its normal rigid state."

In this regard, the securing mechanism of the prior art identified by Groiso offers little beyond the teachings of Groiso itself. Consider, e.g., the following passage in column 4, lines 27-39 of Groiso and a portion of the associated Figure 2:

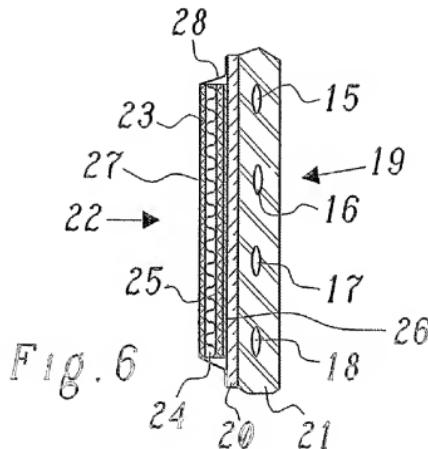
Splint-plate 2 includes a ribbon or strip 3, which is made from a non-stretchable and thermally resistant material. The strip 3 is joined, at one of its ends 4, to the splint-plate 2, by means of any suitable joining means 8, such as a pair of stainless rivets. The other end 5 of the strip 3 includes locking means 6 which are complementary with corresponding locking means 7 located in the splintplate 2. The locking means 6 and 7 may be of any suitable nature, such as typical hook and loop means. In any case, the locking means 6, 7 and the joining means 8 must be capable of firmly retaining the splint-plate around the body member of the patient, at least until the plate 2 is rigid.



Just as in the prior art to which Groiso refers, the Groiso device itself relies a ribbon/strip to travel fully around the body part to be supported. The ribbon/strip is secured to itself or the splint in such a way that it is the compressive force applied by the ribbon/strip that attempts to hold the splint in place on the skin over the fracture. Correspondingly, any component identified as an adhesive in either the Groiso device or the prior art to which Groiso refers exists to secure the ribbon/strip to either itself or the splint.

Neither Groiso, the prior art to which Groiso refers, nor any prior art known to the applicant offers any suggestion whatsoever of adhering the splint to the skin that overlies the fracture. Such a feature appears nowhere other than the present application, and this feature is now more explicitly recited in the amended claims.

By way of comparison, consider present Figure 6:



In this illustration, ribs 15-18 are embedded in intercostals musculature 21, over which lies skin/fat tissue layer 20. Elements 23-28 make up this particular embodiment of the overall device 22. Of these, adhesive layer 26 of the device is in direct contact with the patient's skin. This feature is utterly unknown in the known prior art, including the Groiso reference and any known combination of such reference with any other prior art.

The present device takes a completely new approach to treating rib fractures. The Applicant has discovered, in stark contrast to all conventional wisdom in medicine, that it

possible to adhere a rigid formable splint element that has been curved into the proper conforming shape directly to the skin over a rib fracture. Beyond the possibility, the analgesic properties of such a device in application to the comfort and healing of the patient are a considerable improvement over any other approach.

Devices such as that of Groiso and all other known art in this field are inherently predicated on the assumption that the rigid splint cannot be adhered to the skin. Groiso teaches that a rigid splint is possible, but cannot be attached directly to the skin. Alternatively, the earlier applied Rolnick reference teaches adhesion to the skin, but specifically requires that the device be elastic. For this reason, it has been universally assumed that either some sort of compressive wrap is necessary (Groiso) or the device must be elastic (Rolnick).

The present invention demonstrates for the first time that these long held assumptions are not correct, yet the present Applicant is the first to discover that this is the case.

In the interest of sharpening the distinction between the present device and the teachings of the prior art, Applicant has amended each of the independent claims to recite that the adhesive, in the form of a means for adhering the device to the skin of the patient, is present on the face of

the device that is to be brought into contact with such skin.  
Moreover, such device is, at the same time, both rigid and  
formable.

The Office Action rejects the following claims under 35 U.S.C. §103(a) as unpatentable over the Groiso reference discussed in detail above in view of the following secondary references: claim 16 in view of Tornai; claims 20, 23, 29, 30, and 39 in view of Bolla et al.; and claims 37 and 38 in view of Nagai et al.

In each of these claims, the primary Groiso reference is offered for teaching the same features for which it is offered as to the independent claim 15. Applicant has amended independent claims 29 and 30 in a manner similar to that of claim 15. Each such claim now specifically recites the relationship between the rigid, formable splint element and the means for adhering in such a way that the means for adhering is on the face that is to be adhered to the skin of the patient. Regardless of which of the secondary references the Groiso patent is combined with, there exists no such combination that serves to render the obvious the device as claimed. The claimed device is entirely at odds with the known prior art, which does not contemplate a rigid, formable splint element that is constructed to be adhered to the skin of a patient over a rib fracture.

For at least this reason, Applicant respectfully suggests that each of such obviousness rejections cannot reasonably be maintained, and reconsideration and withdrawal of each is therefore respectfully requested.

The Office Action explicitly notes the allowability of claims 24-27 and 31 but for their dependence from rejected base claims. In light of the present amendments, Applicant respectfully suggests that all claims remaining in the application are in condition for allowance.

If the Examiner has any questions he is invited to contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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